# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fipralone duo 50 mg/ 60 mg spot-on solution for cats

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.5 ml pipette contains:

**Active substances:**
Fipronil 50 mg
Pyriproxyfen 60 mg

**Excipients:**

| **Qualitative composition of excipients and other constituents** | **Quantitative composition if that information is essential for proper administration of the veterinary medicinal product** |
|---|---|
| Butylhydroxyanisole E320 | 0.1 mg |
| Butylhydroxytoluene E321 | 0.05 mg |
| Diethylene glycol monoethyl ether | |

Clear, colourless to yellowish solution.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Cats.

### 3.2 Indications for use for each target species

In cats, to be used against infestations with fleas alone or in association with ticks.

Against fleas:
Treatment and prevention of infestations by fleas *(Ctenocephalides felis).* One treatment prevents further infestations for 5 weeks.
Prevention of the multiplication of fleas by preventing flea eggs developing into adult fleas for 12 weeks after application.

Against ticks:
Treatment of infestations by ticks (*Ixodes ricinus* and *Rhipicephalus turanicus*).
One treatment provides persistent acaricidal efficacy for one week.
If ticks are present at the time of application, not all ticks may be killed within 48 hours.

## 3.3 Contraindications

Do not use in rabbits, as adverse reactions and even death could occur.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

## 3.4 Special warnings

Wetting of the haircoat with water 2 hours before product application and twice during the claimed period of efficacy against fleas (at two week intervals against adult fleas or four week intervals against developing flea stages) was investigated during two laboratory studies. Wetting of the haircoat with water as described did not adversely affect veterinary medicinal product effectiveness.
The impact of shampooing on veterinary medicinal product effectiveness has not been investigated. If a cat requires shampooing it is recommended that this is done before applying the veterinary medicinal product.

At the beginning of the control measures, in the case of an infestation, the animal's basket, bedding and regular resting areas such as carpets and soft furnishings should be treated, with a suitable insecticide and vacuumed regularly.

To reduce environmental flea challenge, all animals living in the same household should also be treated with a suitable flea control product.

The veterinary medicinal product does not prevent ticks from attaching to animals. If the animal has been treated prior to exposure to the ticks, the ticks will be killed within 48 hours after attachment. This will usually be prior to engorgement, minimising but not excluding the risk of transmission of diseases.
Once dead, ticks will often drop off the animal. Any remaining ticks should be carefully removed, ensuring that their mouth parts are not left within the skin.

## 3.5 Special precautions for use

<u>Special precautions for safe use in the target species:</u>
For external use only. Do not administer orally.
Animals should be weighed accurately prior to treatment.
The safety of the veterinary medicinal product has not been established in cats younger than 10 weeks of age or in cats weighing less than 1.0 kg.
Avoid contact with the animal’s eyes. In the case of accidental eye contact, flush the eyes with water.
Care should be taken to apply the veterinary medicinal product correctly as described under section 3.9. Do not apply the veterinary medicinal product on wounds or damaged skin. It is important to make sure that the veterinary medicinal product is applied directly onto an area of dry skin where the animal cannot lick it off and to make sure that animals do not lick each other following treatment.

The use of the veterinary medicinal product has not been studied in sick or debilitated cats. Use in sick or debilitated animals only in accordance with a benefit-risk assessment performed by the responsible veterinarian.

In the absence of additional safety studies, do not repeat the treatment at intervals of less than 4 weeks.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
The veterinary medicinal product may cause neurotoxicity. The veterinary medicinal product may be harmful if swallowed.
Avoid ingestion including hand to mouth contact.
Do not smoke, drink or eat during application.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
This veterinary medicinal product can cause eye and mucous membrane irritation.
Avoid contact with skin, eye and mouth, including hand to eye contact.
In the case of accidental skin or eye contact, immediately and thoroughly flush with water.
If skin or eye irritation persists, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after use.
Treated animals should not be handled until the application site is dry, and children should not be allowed to play with treated animals until the application site is dry. It is therefore recommended that animals are not treated during the day, but should be treated during the early evening, and that recently treated animals should not be allowed to sleep with owners, especially children.
Keep the pipettes in the original packaging until ready for use and dispose of used pipettes immediately.

Special precautions for the protection of the environment:
Not applicable.

Other precautions:
The veterinary medicinal product may have adverse effects on painted, varnished or other household surfaces or furnishings. Allow the application site to dry before permitting contact with such materials.

### 3.6 Adverse events

Cats:

| | |
|---|---|
| Very rare<br>(<1 animal / 10,000 animals treated, including isolated reports): | Application site reaction[1] (e.g. Application site skin squamosis, Application site alopecia, Application site pruritus, Application site erythema, Application site skin discolouration)<br><br>Generalised itching, Alopecia<br><br>Hypersalivation, Vomiting<br><br>Neurological disorder[2] (e.g. Hyperaesthesia, Central nervous system depression, Neurological symptoms)<br><br>Respiratory signs |
| Undetermined frequency | Application site greasy fur[1,3], Application site skin scaling[1,3,4], |

[1]Transient
[2]Reversible
[3]Cosmetic effect
[4]Slight

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

### 3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Pregnancy and lactation:
Laboratory studies using fipronil and pyriproxyfen have not produced any evidence of teratogenic or embryotoxic effects. Use only according to the benefit-risk assessment by the responsible veterinarian.

### 3.8 Interaction with other medicinal products and other forms of interaction

None known.

### 3.9 Administration routes and dosage

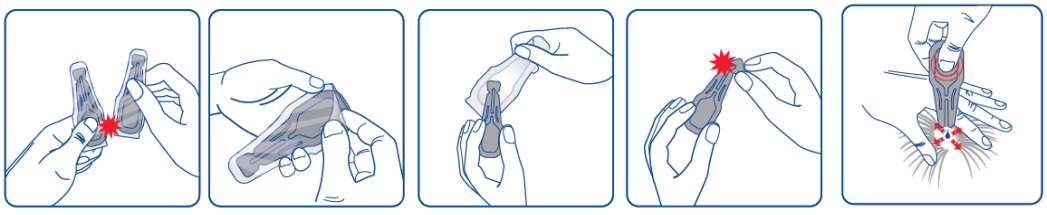
Spot-on use.

Dosage:
For a cat weighing 1-6 kg apply one pipette of 0.5 ml per cat corresponding to the minimum recommended dose of 8.3 mg fipronil/kg b.w. and 10 mg pyriproxyfen/kg b.w.

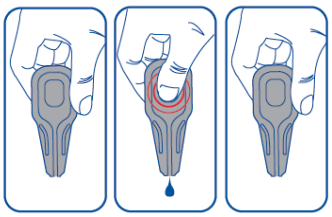
| Cat weight | Pipette volume | Fipronil (mg) | Pyriproxyfen (mg) |
|---|---|---|---|
| 1-6 kg | 0.5 ml | 50 | 60 |
| >6-12 kg | 1 ml | 100 | 120 |

For a cat weighing more than 6 kg a recommended dose of 1 ml should be applied, which can be achieved by applying two 0.5 ml pipettes.

Method of administration:
Remove the pipette from the overblister. Hold the pipette upright. Tap the narrow part of the pipette to ensure that the contents are within the main body of the pipette. Break the snap-off top of the spot-on pipette along the scored line.
Part the coat on the back of neck area until the skin is visible. Place the tip of the pipette on the skin and squeeze firmly several times to empty the contents evenly at one or two spots. Ensure the solution is applied to healthy skin only and avoid superficial application to the cat's hair or run off.



Drop stop system (the product is released only by pressing the body of the pipette).



For optimal control of flea and tick infestations and flea multiplication, the treatment schedule can be based on the local epidemiological situation. However, in the absence of additional safety studies, do not repeat the treatment at intervals of less than 4 weeks (see section 3.10).

### 3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No serious adverse effects were observed in a target animal safety study in 10-week old kittens treated with up to 5 times the maximum recommended dose 3 times at intervals of 4 weeks and with the maximum recommended dose 6 times at intervals of 4 weeks.
The risk of experiencing adverse reactions (see section 3.6) may however increase with overdosing, so animals should always be treated with correct pipette size according to bodyweight.

### 3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

### 3.12 Withdrawal periods

Not applicable.

## 4. PHARMACOLOGICAL INFORMATION

### 4.1 ATCvet code: QP53AX65.

### 4.2 Pharmacodynamics

**Fipronil** is an insecticide and acaricide belonging to the phenylpyrazole family. Fipronil and its metabolite fipronil sulfone act at ligand-gated chloride channels, in particular those gated by the neurotransmitter gamma-aminobutyric acid (GABA) as well as desensitising (D) and non-desensitising (N) channels gated by glutamate (Glu, unique invertebrate ligand-gated chloride channels), thereby blocking pre- and post-synaptic transfer of chloride ions across cell membranes. This results in uncontrolled activity of the central nervous system and death of insects or acari.

**Pyriproxyfen** is an insect growth regulator (IGR) of the class of compounds known as juvenile hormone analogues. Pyriproxyfen sterilises adult fleas and inhibits the development of immature stages. The molecule prevents, by contact, the emergence of adult insects by blocking the development of eggs (ovicidal effect), larvae and pupae (larvicidal effect), which are subsequently eliminated. Following contact and/or ingestion by adult fleas, the molecule also acts by sterilising eggs during their maturation and before

being laid. The molecule prevents contamination of the environment of treated animals with the immature stages of fleas.

Combination of fipronil and pyriproxyfen provides an insecticidal and acaricidal activity against fleas (*Ctenocephalides felis*), ticks (*Rhipicephalus turanicus*, *Ixodes ricinus*) in addition to preventing flea eggs developing into adult fleas.
Such combination provides an integrated flea control which can be used against infestations with fleas alone or in association with ticks.

### 4.3 Pharmacokinetics

Following topical application of the veterinary medicinal product, under the normal conditions of use, fipronil and pyriproxyfen are well distributed in the haircoat of the cat from the first day post application. The major metabolite of fipronil is the sulfone derivative, which also possesses insecticidal and acaricidal properties.

The concentrations of fipronil and pyriproxyfen in the haircoat decrease over time but both active substances are present for at least 84 days after application (i.e. above the lower limit of quantification (LOQ) 100 ng/g for fipronil and 50 ng/g for pyriproxyfen). Concentrations of fipronil sulfone remained below the lower limit of quantification (LOQ 100 ng/ml) after product application.

The plasmatic peaks of fipronil and pyriproxyfen concentration are rapidly reached 1 day after administration. Concentrations of fipronil are quantifiable in all cats up to 3 days after application (LOQ 1 ng/ml). Concentrations of pyriproxyfen are quantifiable in all cats up to 42 days after application (LOQ 0.2 ng/ml). Concentrations of fipronil sulfone remained below the lower limit of quantification (LOQ 1 ng/ml) after product application.

## 5. PHARMACEUTICAL PARTICULARS

### 5.1 Major incompatibilities

None known.

### 5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

### 5.3 Special precautions for storage

Do not store above 30 °C.
Store in a dry place.
Keep the blister pack in the outer carton in order to protect from light.

### 5.4 Nature and composition of immediate packaging

Transparent multi-layer plastic single-dose pipettes containing 0.5 ml obtained by thermoforming a transparent bottom complex (polyacrylonitrile-methacrylate or polyethylene-ethylene vinyl alcohol-polyethylene), polypropylene, cyclic olefin copolymer, polypropylene) and closed by heat sealing with a lid complex (polyacrylonitrile-methacrylate or polyethylene-ethylene vinyl alcohol-polyethylene), aluminium, polyethylene-terephthalate).

The boxes contain individual pipette(s) placed in overblister(s) made from polypropylene, cyclic olefin copolymer, polypropylene and closed with lid made from polyethylene-terephthalate, aluminium, polypropylene.

Boxes of 1, 2, 3, 4, and 6 pipettes.

Not all pack sizes may be marketed.

### 5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as fipronil and pyriproxyfen may be dangerous for fish and other aquatic organisms.

Do not contaminate ponds, waterways or ditches with the veterinary medicinal product or empty container.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

## 6. NAME OF THE MARKETING AUTHORISATION HOLDER

Alfamed

## 7. MARKETING AUTHORISATION NUMBER

Vm 17902/3011

## 8. DATE OF FIRST AUTHORISATION

04 September 2015

## 9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

July 2025

## 10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

*Gavin Hall*

Approved: 27 August 2025